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Richard John Bartz
Suite 350
6750 France Avenue South
Edina, MN 55435

EXAMINER	
HUYNH, PHUONG N	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/025,567
Filing Date: December 26, 2001
Appellant(s): NASH ET AL.

Richard John Bartz
For Appellant

EXAMINER'S ANSWER

This is in response to the amended appeal brief filed 10/31/05 appealing from the Office action mailed 9/30/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Applications 09/616,843 and 10/038260 are pending before the Board of Appeals and Interferences.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

Claims 1, 3, 5-7 and 12-29 are pending.

Claims 1 and 6 have been amended subsequent to the Final rejection.

This appeal involves claims 1, 3, 5-7 and 12-29, which can be found in the Claims appendix of the amended Brief filed 10/31/05.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is substantially correct. The part that is incorrect is on page 3 of the brief is where "the binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens". There is no showing, i.e., binding assays in the specification as filed that any IgM and/or IgA increase(s) the binding of IgY to any protein-wasting immunogen. In fact, the specification discloses "Once immunized the hen lay[er]s the unique IgY type immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies." see specification page 10, lines 2-5.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

The change is as follows: The rejection of claims 6-7 and 22-29 under 35 U.S.C. 112, first paragraph for new matter is hereby withdrawn in view of the fact that "living being" is no longer recited in said claims.

The issues on appeal are as follow:

A. Whether claims 1, 3, 5-7, and 12-29 are enabled under 35 U.S.C. 112, first paragraph.

B. Whether claims 1, 3, 5-7, and 12-29 have written support under 35 U.S.C. 112, first paragraph.

C. Whether claims 5 and 12 contain new matter under 35 U.S.C. 112, first paragraph.

D. Whether claims 1, 3, 5, 13, 16 and 19 are obvious under 35 U.S.C. 103(a) over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

E. Whether claims 14-15, 17-18 and 20-21 are obvious under 35 U.S.C. 103(a) over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 1, 3, 5, 13, 16 and 19 mentioned above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

F. Whether claim 5 under 35 U.S.C. 103(a) is obvious over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) and Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892).

G. Whether claims 6-7, 12, 22 and 23 are obvious under 35 U.S.C. 103(a) over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

H. Whether claims 24-29 are obvious under 35 U.S.C. 103(a) over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,741,489	**Pimentel**	**Apr. 21, 1998**
5,080,895	**Tokoro**	**Jan. 14, 1992**
4,166,867	**Betz**	**Sept. 4, 1979**
4,748,018	**Stolle**	**May 31, 1988**
6,086,878	**Adalsteinsson**	**Jul. 11, 2000**

Stryer et al, in Biochemistry, Third edition, W H Freeman Company, New York, pages 31-33, 1998.

Kuby et al, Immunology, Second edition, pages 86-96, 1994.

Abaza et al, J of Protein Chemistry 11(5): 433-444, 1992.

Kaspers *et al*, Zentralbl Veterinarmed A 43(4): 225-31, June 1996.

Krause *et al*, Appl Environ Microbiol 62 (3): 815-21; 1996.

Sugita-Konishi *et al*, Biosci Biotechnol Biochem 60(5): 886-8, May 1996.

Yokoyama *et al*, Vaccine 16(4): 388-93, Feb 1998.

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

1. Claims 1, 3, 5-7, and 12-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria in the rumen or intestinal tracts of said food animal wherein the colony-forming bacteria are selected from the group consisting of *P. anaerobius, C. sticklandii, C. aminophilium, E. Coli, Listeria, Salmonella* and *Campylobacter* produced by the method inoculating female birds, in or about to reach their egg laying age, with said colony-forming bacteria; allowing a period of time sufficient to permit the production in the bird of antibody to said targeted immunogen; Harvesting the eggs laid by the birds; Separating the antibody-containing contents of said eggs from the shells and Drying said separated antibody-containing contents of said eggs, **does not** reasonably provide enablement for *any* microbial adherence inhibitor for administration to food animal or any living being to inhibit the adherence of any colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by inoculating female chickens or birds *any* target colony-forming immunogen as set forth in claims 1, 3, 5-7, and 12-29 to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only five microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming bacteria selected from the

group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157* to inhibit the adherence of said colony-forming bacteria in the rumen or intestinal track and thereby decreasing the waste of dietary protein and promoting the growth of the food animal. The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157*, harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to make much less how to use any microbial adherence inhibitor in form of egg antibody that binds to *any* undisclosed colony-forming immunogen because "immunogen" could be peptide, protein, bacteria, virus, or parasite. However, peptide or protein antigen without the specific amino acid sequence has no structure. Further, there is inadequate guidance as to which undisclosed colony forming immunogen such as bacteria, parasite, or virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the colony-forming "immunogen" such as bacteria, virus, or parasite other the specific bacteria mentioned above has been identified, the microbial adherence inhibitor in form of egg antibody to that binds to the undisclosed colony-forming immunogen cannot be made. Given the indefinite number of colony-forming immunogen, there is insufficient guidance as to the binding specificity of the microbial adherence inhibitor.

Stryer *et al*, of record, teach that a protein (immunogen) is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages). Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al*, of record, teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Given the indefinite number of undisclosed colony-forming immunogen, it is unpredictable which undisclosed microbial inhibitor in the form of chicken antibody IgY including IgA and IgM in the albumin would bind specifically to said undisclosed colony-forming immunogen, in turn, would be useful for inhibiting the adherence of any protein wasting immunogen in the food animals or any living being. Given the indefinite number of undisclosed microbial adherence inhibitor, there is no *in vivo* working example demonstrating that the claimed microbial adherence inhibitor is effective for inhibiting the adherence of all colony-forming immunogen (bacteria, parasites, virus, etc), let alone preventing (claim 22) the adherence of targeted colony-forming immunogens in the rumen or intestinal tracts of food animal.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

2. Claims 1, 3, 5-7, and 12-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* microbial adherence inhibitor for administration to food animal or any living being to inhibit the adherence of any colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by inoculating female chickens or birds *any* target colony-forming immunogen as set forth in claims 1, 3, 5-7, and 12-29 to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

The specification discloses only five microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming *bacteria* selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157* to

inhibit the adherence of said colony-forming bacteria in the rumen or intestinal track and thereby decreasing the waste of dietary protein and promoting the growth of the food animal. The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157,* harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

Other the specific microbial adherence inhibitor in the form of IgY that inhibits the specific colony forming bacteria *P. anaerobius, C. sticklandii, C. aminophilium, E coli, Listeria, Salmonella* from adhering to the rumen or digestive track of food animal, there is inadequate written description about the microbial adherence inhibitor that inhibit the adherence of which undisclosed colony-forming immunogen because "immunogen" could be peptide, or protein antigen and without the specific amino acid sequence has no structure. Further, there is inadequate written description about which undisclosed colony forming immunogen such as bacteria, parasite, and virus causes food wasting and reduce the growth of which food animal or living being. Until the colony-forming immunogen has been identified, the microbial adherence inhibitor in form of egg antibody to that binds to the undisclosed colony-forming immunogen cannot be made. Given the infinite number of undisclosed colony-forming immunogen, the said undisclosed colony forming immunogen has not been adequately described. Since the immunogen is not adequately described, the binding specificity of microbial adherence inhibitor in the form of IgY including IgA and IgM to that undisclosed immunogen is not adequately described.

Since the specification discloses only a microbial inhibitor in the form of IgY produced by inoculating the bird with the following six colony-forming immunogens such as bacteria selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella,* and *Campylobacter*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of colony-forming immunogens, in turn, the microbial inhibitor to said undisclosed colony-forming immunogens. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

3. Claims 5 and 12 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The "living being" in Claims 5 and 12 represents a departure from the specification and the claims as originally filed. The passages pointed out by applicant in the amendment filed 10/23/03 do not provide a clear support for the said phrase.

4. Claims 1, 3, 5, 13, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that inhibits the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines

1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claims 1 and 5 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals.

The claimed invention in claim 3 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 13 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*.

The claimed invention in claim 16 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. sticklandii*.

The claimed invention in claim 19 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. aminophilium*.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489

patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document, abstract, in particular). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen or bacteria such as the *E coli* as taught by the '895 patent for the bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* that are responsible for nutrition depletion of cattle as taught by Krause *et al* for producing egg antibody and drying the separated entire contents whole egg (white and yolk) antibody without first isolating the antibodies from the yolk as taught by the '489 patent since (IgY) is primary the immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '895 patent teaches egg antibody is particularly advantageous due the fact that the procedure of making egg antibody is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '489 patent teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when are contained in the spray-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Krause *et al* teach bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document).

5. Claims 14-15, 17-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract, June 1996; PTO 892), US Pat No 5,741,489

(of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 1, 3, 5, 13, 16 and 19 mentioned above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Kasper et al, the '489 patent, and Krause et al have been discussed supra.

The claimed invention in claim 14 differs from the combined teachings of the references only in that the microbial adherence inhibitor wherein the drying of the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs.

The claimed invention in claim 15 differs from the combined teachings of the references only in that the microbial adherence inhibitor wherein the dry feed materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46, col. 5, lines 5-10, in particular). The '878 patent teaches various methods are known for drying eggs (see col. 9, lines 28-31, in particular).

The '867 patent teaches high performance palatable horse feed carrier such as soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat the feed carrier material as taught by the '878 patent with the entire contents of said eggs containing antibody that binds specifically to *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* as taught by the '895 patent, Kasper et al, the '489 patent, and Krause et al on the feed material such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '878 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) and Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines

1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 5 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and wherein the colony-forming immunogen is from the class consisting of *Listeria, Salmonella* and *Campylobacter.*

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference egg antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogens such as bacterium as *E coli, Listeria, Salmonella and Campylobacter*, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds

to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that avian antibody produced by domesticated fowl which has been immunized against with any antigen of interested is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Yokoyama *et al* teach a microbial adherence inhibitor such as chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella. The reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen or bacteria such as the *E coli* as taught by the '895 patent for the bacteria such as *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent or the *Salamonella* as taught by Sugita-Konishi *et al* or the (OMP) of Salmonella as taught by Yokoyama *et al* for a microbial adherence inhibitor in the form of IgY, IgA and IgM antibody as taught by Kaspers *et al* to said *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent, Sugita-Konishi *et al* or Yokoyama *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Yokoyama *et al* teach IgY antibody to colony-forming immunogen such as Salmonella inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). Sugita-Konishi *et al* teach that egg antibody to *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). The '018 patent teaches that IgY

antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular) is useful for a method of passive immunity (See abstract, in particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is the primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

7. Claims 6-7, 12, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the

animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claims 6 and 12 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and coating said dry feed carrier material with the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive track by binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulin.

The claimed invention in claim 12 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and coating said dry feed carrier material with the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive track by binding of the IgY immunoglobulins to the colony-forming

immunogen being assisted by the IgM and IgA immunoglobulin wherein the colony forming immunogens are from the class consisting of *E. Coli, Listeria, Salmonella* and *Campylobacter*.

The claimed invention in claims 7 and 23 differs from the combined teachings of the reference only in that the microbial adherence inhibitor wherein the dry feed materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *E coli, Listeria, Salmonella and Campylobacter*, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference IgY inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Yokoyama *et al* teach a microbial adherence inhibitor in the form of chicken egg yolk homotypic antibodies (IgY) specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella. The reference IgY inhibits the adhesion of

Salamonella to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to produce IgY antibodies that bind to colony forming immunogen or bacteria that forms colony in the digestive tract such as *E. Coli* as taught by the '895 patent or *Listeria, Salmonella* and *Campylobacter* as taught by the '018 patent that inhibits the adhesion of said immunogen to the digestive tract as taught by Sugita-Konishi *et al and* Yokoyama *et al* by incoculating the birds with said immunogen, harvesting the eggs laid by the birds, separating the entire contents of harvested eggs from the shells as taught by the '895 patent, the '018 patent and coating the dry feed carrier such as soybean hulls, rice hulls and cottonseed hulls as taught by the '867 patent, and the '878 patent with the entire contents of the eggs (whole egg) as taught by the '489 patent that contains IgY in the yolks while IgM and IgA immunoglobulins in the albumin of the egg as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '895 patent teaches that egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '018 patent teaches that the avian antibody produced by domesticated

fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular). Sugita-Konishi *et al* teach IgY antibody obtained from hens immunized with *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach that IgY inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis (See abstract, (See abstract, and Materials and Methods, in particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried on carrier and then mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, lines 1-2, col. 5, line 52-56, in particular) and such whole antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

8. Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (or record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with

the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 24 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by inoculating female birds, in or about to reach their egg laying age, with P antigen with *P. anaerobius,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

The claimed invention in claims 25, 27 and 29 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 26 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by inoculating female birds, in or about to reach their egg laying age, with P antigen with CS antigen from *C. sticklandii,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

The claimed invention in claim 28 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilium,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489

patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen or bacteria such as the *E coli* as taught by the '895 patent for the immunogen such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* as taught by Krause *et al* to produce IgY antibodies that bind specifically to said colony forming immunogen to inhibit the adhesion of said immunogen in the digestive track by immunizing hens with said immunogens, harvesting the eggs laid by the birds as taught by the '895 patent and the '018 patent and coating the dry feed carrier such as soybean hulls, rice hulls and cottonseed hulls as taught by the '867 patent, and the '878 patent with the entire contents of the eggs (whole egg) as taught by the '489 patent that contains IgY in the yolks while IgM and IgA immunoglobulins in the albumin of the egg as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '895 patent teaches that egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular). Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

(10) Response to Argument

Enablement Rejection - 35 USC § 112 First Paragraph

At page 14-16 of the Brief, Appellant submits that the specification describes the methods of Selection of Egg laying avian hens, pages 12-13, Preparation of Stock Culture, page 12, Preparation of H antigens for Immunogens, pages 13-14, Preparation of O antigens for immunogens, pages 14-15; Preparation of A antigen for immunogen, pages 1 5-16, Preparation of P antigen for immunogen, pages 16-17, Preparation of CA antigen for immunogen, pages 17-18, Analysis of individual eggs and serum over time, page 19; immunization of chickens with immunogens, page 20-22; and Feeding of Cattle, pages 27-28. The specification contains a detailed description and best mode of Appellants' process of promoting the growth of food

animals, such as cattle, by decreasing the waste of dietary protein caused by the presence of a protein-wasting colony-forming immunogen in the rumen of intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject microbial adherence inhibitor. The immunogen is limited to a colon-forming immunogen. Appellants have provided a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming immunogen. These immunogens are well known protein-wasting immunogens. The species of immunogens are identified from a class consisting of *P. anqerobius, C. sticklandii, C. aminophilium, E. coli, Listeria, Salmonella* and *Campylobacter*. Appellants have also disclosed other colony-forming organisms including Actinomycetes, Streptococcus, Bacteriodes such as ruminicola, Crytococcus and yeast molds. Specification, page 2, ! 0006, lines 1-2. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by Stolle et al '018 in column 5, lines 5-35. Claims 6 and 22 particularly point out and distinctly claim the subject matter of Appellants' microbial adherence inhibitor as described in the written description of the specification.

Appellants' arguments filed 10/30/05 have been fully considered but are not found persuasive. Appellants' argument seems to go more toward description rather than enablement. The examiner's rejection is based on the scope of enablement, not lack of written description.

Claims 1, 6-7 and 22-23 encompasses any microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any and all targeted "colony-forming immunogen" by inoculating the female chickens with any targeted colony-forming immunogen and when administered to any food animals, the IgY immunoglobulin promotes the growth of all food animals by decreasing the waste of dietary protein and the binding of IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the targeted colony-forming immunogen to adhere to the rumen or intestinal tracts of the animals. Claims 3, 13-21 and 24-29 encompasses any and all microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any "colony-forming immunogen" from the class of *P. anaerobius, C. Sticklandii and C. aminophilium* for administration to food animals. Claims 5 and 12 encompasses any and all microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any "colony-forming immunogen" from the class of *E coli,*

Listeria, Salmonella and Campylobacter for administration to any living being, i.e. human, whale.

The specification discloses only colony forming *bacteria* selected from the group consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E coli serogroup 0157*. The specification discloses microbial adherence inhibitor or Avian antibody is produced by the method of growing said bacteria under specific condition to stimulate the expression of adherin or somatic antigen on the bacteria (pages 12-17), inoculating female chicken with the specific bacterial lysate or supernatant from bacteria such as *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157*, harvesting the eggs (page 20), whole egg containing the IgY in the yolk and IgM and IgA in the albumin is mixed, pasteurized, and store until dried or sprayed onto carriers such as pelleted soybean hulls as feed additive (page 22-23) prior to mixing with feed to feed animal to inhibit the adherence of said specific bacteria in the intestinal tracts of food animal and thereby promote the growth of the animal.

The specification does not teach how to make all microbial adherence inhibitors such as IgY immunoglobulins that bind to all "colony-forming immunogen". This is because of the inadequate guidance as to the structure of the "colony-forming immunogen". The term "immunogen" could be any protein, peptide, bacteria, parasites, virus, any molecules or "adherins" or somatic antigens on the surface of any colonizing microorganisms such as bacteria, viruses and parasites, etc as disclosed on page 12, line 8-10 of the specification.

Without the specific amino acid sequence, or biochemical properties of "immunogen", it has no structure. Even if the "colony-forming immunogen" is limited to the organism such as bacteria, the specification discloses the bacteria containing certain antigens such as H antigen, O antigen, A antigen, and WC antigen on *E coli* must be cultured in a specific medium or condition (see Example 3-5 on page 13-15 of the specification). Given the unlimited number of immunogen, there is insufficient guidance as to which condition medium to grow any and all immunogen such as bacteria, virus, parasite, in turn, making egg antibody to those undisclosed immunogen as a microbial inhibitor. Further, there is a lack of guidance or assays to enable one skill in the art to identify other immunogen such as adherins or somatic antigens or organism such as parasite that is responsible for wasting dietary protein when adhere to the intestinal tract of any food animal or any and all living being.

Although the method of making IgY antibody is known in the art, the actual binding of IgY immunoglobulins to the specific bacteria and "being assisted by the IgM and IgA

immunoglobulins" per se in the digestive track remain to be demonstrated. This is particularly true when the immunogen is a parasite where the organism has different life cycle. Given the teachings of the specification, it is not clear that avian antibody binding to a parasite at one stage of its life cycle could effectively inhibit the adherence of the parasite in the digestive tract of any and all living being. Until the "colony-forming immunogen" has been identified as the culprit responsible for wasting dietary protein in a living being, it is unpredictable which undisclosed colony-forming immunogen would colonize the rumen or intestinal tracts and wasting dietary protein in which food animal, or which living being.

Given the unlimited number of microbial adherence inhibitor in the form of IgY, there is insufficient guidance as to the *binding specificity* of all microbial adherence inhibitor, in turn, would be useful for inhibiting the colony-forming immunogen to adhere to the rumen or intestinal tracts of all animals, let alone promoting the growth of all food animal by decreasing the waste of dietary protein.

Stryer *et al*, of record, teach that a protein (immunogen) is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages).

Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al*, of record, teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Given the unlimited number of microbial inhibitor, there is no *in vivo* working example demonstrating that any of the egg antibody inhibits the adherence of any bacteria in the digestive tract of any living being.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Written Description Rejection - 35 USC § 112 First Paragraph

At pages 17-18 of the Brief, Appellants state that the specification provides a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming immunogen. These immunogens are well known protein-wasting immunogens. The species of immunogens are identified from a class consisting of *P. anaerobius, C. sticklandii, C. aminophilium, E. coli, Listeria, Salmonella* and *Campylobacter*. Appellants have also disclosed other colony-forming organisms including Actinomycetes, Streptococcus, Bacteriodes such as ruminicola, Crytococcus and yeast molds. Specification, page 2, 0006, lines 1-2. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by Stolle et al '018 in column 5, lines 5-35. Claims 6 and 22 particularly point out and distinctly claim the subject matter of Appellants' microbial adherence inhibitor as described in the written description of the specification. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. Page 12, ¶, lines 4-6. The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that hen layers the unique IgY types immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Specification page 10, ¶ 0028, lines 12, 13. The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY immunogens to the protein-wasting immunogens as more IgY immunogens are available to [f]bind to the protein-wasting immunogens. The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain

molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal. Appellants have discovered that egg IgY immunoglobulins must bind to protein-wasting immunogens to inhibit adherence of the immunogens in the intestinal tracts of hosts and animals. The totality of the teachings of the prior art do not reveal this discovery and advantageous results.

Appellants' arguments filed 10/30/05 have been fully considered but are not found persuasive.

Claims 1, 6-7 and 22-23 encompasses any microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any and all targeted "colony-forming immunogen" by inoculating the female chickens with any targeted colony-forming immunogen and when administered to any food animals, the IgY immunoglobulin promotes the growth of all food animals by decreasing the waste of dietary protein and the binding of IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the targeted colony-forming immunogen to adhere to the rumen or intestinal tracts of the animals. Claims 3, 13-21 and 24-29 encompasses any and all microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any "colony-forming immunogen" from the class of *P. anaerobius, C. Sticklandii and C. aminophilium* for administration to food animals. Claims 5 and 12 encompasses any and all microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any "colony-forming immunogen" from the class of *E coli, Listeria, Salmonella and Campylobacter* for administration to any living being, i.e. human, whale.

The specification discloses only colony forming *bacteria* selected from the group consisting of *P. anaerobius, C. sticklandii, C. aminophilum, E coli serogroup 0157.* The specification discloses microbial adherence inhibitor or avian antibody is produced by the method of growing said bacteria under specific condition to stimulate the expression of adherin or somatic antigen on the bacteria (pages 12-17), inoculating female chicken with the specific bacterial lysate or supernatant from bacteria such as *P. anaerobius, C. sticklandii, C. aminophilum,* and *E coli* serogroup *0157,* harvesting the eggs (page 20), whole egg containing the

IgY in the yolk and IgM and IgA in the albumin is mixed, pasteurized, and store until dried or sprayed onto carriers such as pelleted soybean hulls as feed additive (page 22-23) prior to mixing with feed to feed animal to inhibit the adherence of said specific bacteria in the intestinal tracts of food animal and thereby promote the growth of the animal.

Vas-Cath Inc. V. makurbar, 19 USPQ2d 1111, makes clear that Appellants must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry whatever is now claimed (see page 1117). The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath Inc. V. Makurhar, page 1116).

Other the specific microbial adherence inhibitor in the form of egg antibody that inhibits the specific colony forming bacteria *P. anaerobius, C. sticklandii, C. aminophilium, E coli, Listeria,* and *Salmonella* from adhering to the rumen or digestive track of food animal, there is inadequate written description about the microbial adherence inhibitor that inhibit the adherence of other undisclosed "colony-forming immunogen". This is because the term "immunogen" could be any peptide, any protein any bacteria, any parasites, any virus, any molecules or "adherins" or somatic antigens on the surface of any colonizing microorganisms such as bacteria, viruses and parasites, etc as disclosed on page 12, line 8-10 of the specification. Without the specific amino acid sequence, the immunogen has no structure, much less function.

Furthermore, there is inadequate written description about the binding specificity of all microbial adherence inhibitor given the unlimited number of undisclosed colony-forming immunogen. There is inadequate written description about which undisclosed colony forming immunogen such as bacteria, parasite, and virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the "colony-forming immunogen" has been identified and described, the microbial adherence inhibitor in form of egg antibody to said undisclosed immunogen is not adequately described, let alone the "binding of IgY immunogens to protein-wasting immunogens is being *increased* by the IgM and IgA immunoglobulins". There is no disclosure of any binding assays to show that IgY binding to the immunogen is being help or assisted by IgM and IgA found in the albumin of the egg.

Since the specification discloses only the specific microbial adherence inhibitor to the specific colony forming bacteria selected from the group consisting of *P. anaerobius, C.*

Sticklandii, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella*, and *Campylobacter*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of microbial adherence inhibitor and the number of species of colony-forming immunogen to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In contrast to Appellants' assertion that the "binding of IgY immunogens to protein-wasting immunogens is being *increased* by the IgM and IgA immunoglobulins", the specification on page 10, lines 2-4 discloses that "Once immunized the hen layers the unique IgY types immunoglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies." Neither the specification's description nor the exemplary embodiments provide any evidence that the binding of IgY immunoglobulins (microbial adherence inhibitors) to any colony forming immunogen or bacteria is being *increased* or assisted by the IgM and IgA immunoglobulins.

New Matter Rejection - 35 USC § 112 First Paragraph

At page 18 of the Brief, Appellant submits that The Examiner has characterized this as a new matter rejection. The Examiner contends that the terms "living being" in Claims 5 and 12 departs from the specification as originally filed. The specification describes the microbial adherence inhibitor used for food animals and hosts to inhibit adherence of colony-forming immunogens in the rumen and intestinal tracts. The hosts and animals are living beings as they are alive and exist. The terms living being is not indefinite. The term "hosts" is included in the specification. Specification ¶ 0027, lines 1-2; ¶ 0066, lines 1-2. The terms "living beings" as the live hosts in Claims 5 and 12 is not new matter to these claims.

Appellants' arguments filed 10/30/05 have been fully considered but are not found persuasive.

Claims 5 and 12 encompasses any and all microbial adherence inhibitor in the form of avian antibody (IgY immunoglobulin) to any "colony-forming immunogen" from the class of *E coli, Listeria, Salmonella and Campylobacter* for administration to any "living being", i.e. human, whale, not necessary limited to food animal as disclosed in the specification as filed. The term "living being" encompassed humans is not disclosed in the specification as filed.

The specification discloses microbial adherence inhibitor, in the form of fowl egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of **host food animals**, see specification, page 1, ¶ 0001, and abstract of the disclosure. The arguments with respect with to claims 6, 22, 24, 26 and 28 are moot since the term "living being" has been changed to "food animals".

Claims Rejection - 35 USC § 103

Claims 1, 3, 5, 13, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

At page 19-20 of the Brief, Appellants summarize various case laws. At pages 21 of the Brief, Appellants submit that the prior art or record does not contain a clear and particular motivation to combine the references as opined by the Examiner. At page 21 of the Brief, appellants summarize the teachings of the primary reference U.S. Patent No. 5,080,895 (Tokoro '895) in all of the rejections baked upon 35 U.S.C. 103(a). Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdspersons to treat scours (diarrhea in cattle caused by intestinal infection). Tokoro '895 is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in Tokoro '895 of an IgY immunoglobulin that binds to colony-forming illness-causing immunogens. The antibody containing substance also is used as a nutrition supplement, and as an additive to food animals. Tokoro '895 does not provide a teaching of a method for reducing or eliminating the incidence of illnesses caused by colony-forming illness-causing immunogens by binding egg IgY

immunoglobulins combined with IgM and IgA immunoglobulins to illness-causing immunogens to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply and colonize. Tokoro '895 does not coat a dry feed carrier with a mixed egg yolk and albumin product. The object of the Tokoro '895 disclosure is to administer to animals affected by an intestinal infection disease for therapeutic purposes, Column 4, lines 1-4. The Tokoro '895 substance is also useful in the treatment of various infectious diseases, additives in food for livestock, cosmetics and medicines. Column 4, lines 16-21. Appellants' claimed microbial adherence inhibitor is not a treatment of a disease in animals. Appellants' microbial adherence inhibitor is the prevention of illnesses in humans by eliminating the illness-causing immunogens in animal meat. Appellants have discovered a new and useful microbial inhibitor for preventing, as opposed to treating, illnesses in humans caused by a colony-forming illness-causing immunogen. The separate and combined teachings of the second references, Kaspers et al, Sugita-Konishi et al, Krause et al, U.S. Patent No. 6,086,878 (Adalsteinsson et al), U.S. Patent No. 5,741,489 (pimental), U.S. Patent No. 4,748,01 8 (stolle et al), Yokoyama et al and U.S. Patent No. 4,166,867 (Betz et al) with Tokoro '895, do not suggest to one skilled in the art the binding of IgY immunoglobulins to illness-causing immunogens and that this binding is helped or assisted and increased by the IgY and lgA immunoglobulins. There is no clear and particular motivation for a person skilled in the art to combine these references. Further, any combination of these references would not produce Appellants' claimed microbial adherence inhibitor.

Appellants' arguments filed 10/30/05 have been fully considered. Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

It is noted that the microbial adherence inhibitor or avian antibody is to any targeted colony-forming immunogen such as any bacteria, any parasite, any virus, any peptide, or any protein (claim 1).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that inhibits the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular),

allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claims 1 and 5 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals.

The claimed invention in claim 3 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 13 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*.

The claimed invention in claim 16 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. sticklandii*.

The claimed invention in claim 19 differs from the teachings of the reference only in that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. aminophilium*.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document, abstract, in particular). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen or bacteria such as the *E coli* as taught by the '895 patent for the bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* that are responsible for nutrition depletion of cattle as taught by Krause *et al* for producing egg antibody and drying the separated entire contents whole egg (white and yolk) antibody without first isolating the antibodies from the yolk as taught by the '489 patent since (IgY) is primary the immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '895 patent teaches egg antibody is particularly advantageous due the fact that the procedure of making egg antibody is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '489 patent teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when are contained in the spray-dried whole egg

as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Krause *et al* teach bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document).

In response to appellants' argument that the prior art of record does not contain a clear and particular motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine* 5 USPQ2d 1596 (Fed. Cir 1988) and *In re Jones* 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings of the 895 patent pertaining to the IgY antibody that binds specifically to bacteria such as *E coli* and other pathogen and a method of making said antibody that binds to said bacteria for use as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted bacteria in the intestinal tract of the animal, the teachings of Krause indicating bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock, and the teachings of the '489 patent pertaining to whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk would have led one of ordinary skill in the art at the time the invention was made to combine the references to make egg antibody to *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* and drying the entire content of the eggs without heaving to separate the eggs and albumin that are well known in the art. It is common knowledge that IgY types immunoglobulins are found in the yolk while IgM and IgA immunoglobulins are found in the albumin or egg white as taught by Kaspers *et al.* The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144.

In response to appellants' argument that the '895 patent (Tokoro et al) does not coat a dry feed carrier with a mixed egg yolk an albumin product, the '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies

from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular).

At page 21 of the Brief, Appellants submit that Tokoro '895 patent does not provide a teaching of a method for reducing or eliminating the incidence of illnesses caused by colony-forming illness-causing immunogens by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins.

Appellants' arguments filed 10/30/05 have been fully considered. Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

The '895 patent teaches avian antibody can be obtained from overall ovum or the yolk or albumen of an egg laid by a hen (see summary of invention, col. 3, lines 50-53, in particular).. The overall ovum obviously includes the IgY immunoglobulins in the yolk of the eggs and IgM and IgA immunoglublins in the albumin of the eggs as evidence by the teachings of Kaspers *et al.* Further, the '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular).

At page 22 of the Brief, Appellants argue that the combined teachings of the second references do not suggest to one of ordinary skilled in the art the binding of IgY immunoglobulins to illness-causing immunogens and that this binding is helped or assisted and increased by the IgY and IgA immunoglobulins.

Appellants' arguments filed 10/30/05 have been fully considered. Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. There is no evidence such as binding assays in the specification as filed to show the claimed that the binding of IgY to illness-causing immunogens is *increased* or assisted by IgM and IgA. In fact, the specification discloses the albumin helps resistance to whole egg preparations and helps protect the avian antibodies from degradation (see specification, page 4, lines 4-5, in particular). There is no showing that binding of IgY to illness-causing immunogens actually increases in the presence of IgM and/or IgA as argued. Further, the claims are drawn to a product by process. A product is a product, irrespective of its intended use. The combined teachings of the references teach the claimed product.

At page 23-24 of the Brief, Appellant submits that the '895 patent discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herd persons to treat scours (diarrhea in cattle caused by intestinal infection). The '895 is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no is no disclosure in the'895 of an IgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. The '895 does not provide a teaching of a microbial adherence inhibitor produced by the method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *C. anaerobius*, CS antigen from *C sticklandii*, and CA antigen from *C. aminophilium*, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. The pending claims are drawn to a product by process, not a method of treatment using the product as argued. As discussed supra, the '895 patent teaches egg antibody that binds to illness causing colony-forming immunogen such as *E coli* and a method of making and using the antibody as a nutrition supplement, and as an additive to food for food animals.

In response to appellants' argument that the '895 does not provide a teaching of a microbial adherence inhibitor produced by the method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *C. anaerobius*, CS antigen from *C sticklandii*, and CA antigen from *C. aminophilium,* this rejection would have been rejected under 35 U.S.C. 102(b) had the '895 patent teach egg antibody to the specific bacteria *C. anaerobius*, *C sticklandii*, and *C. aminophilium*.

In response to appellant's argument that IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *C. anaerobius*, CS antigen from *C sticklandii*, and CA antigen from *C. aminophilium*, inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply, any egg antibody that binds specifically to bacteria such as *C. anaerobius*, *C sticklandii*, and *C. aminophilium* would obvious prevent these bacteria from

adhering to the rumen or intestinal tracts of food animal, after all, the binding specificity is an inherent function of the antibody.

In response to appellants' argument that protein-wasting immunogens are P antigen from *C. anaerobius*, CS antigen from *C sticklandii*, and CA antigen from *C. aminophilium,* the pending claims are drawn to a product by process. None of the claims recite the step of how to obtain "P antigen" from *C. anaerobius*, CS antigen from *C sticklandii*, and CA antigen from *C. aminophilium* by culturing said bacteria in the specific medium to express the claimed antigen on the surface of the bacteria and then use the antigen to immunize the bird for antibody that binds specifically to said antigen.

At first full paragraph on page 24 of the Brief, Appellant asserts that there is no disclosure in the Kaspers et al publication of IgY, IgM and IgA immunoglobulins whereby the IgY immunoglobulins bind to colony-forming or protein-wasting immunogens with the binding process being assisted by the IgM and IgA immunoglobulins thereby inhibiting the colony forming or protein-wasting immunogens from adhering to the intestinal tracts of animals.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. The specification discloses the albumin helps resistance to whole egg preparations and helps protect the avian antibodies from degradation (see specification, page 4, lines 4-5, in particular). There is no showing that binding of IgY to illness-causing immunogens actually *increases* or *assists* in the presence of IgM and/or IgA as argued. There is no showing in the specification as filed the binding specificity of any of the claimed antibody, much less IgY, IgM and IgA immunoglobulins inhibit the colony forming or protein-wasting immunogens from adhering to the intestinal tracts of any animals. The instant claims are drawn to a product by process. The combined teachings of the reference discussed supra teach the claimed product.

At last paragraph on page 24 of the Brief, Appellants argue that there is no teaching in the '489 patent of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. All pending claims are drawn to a product by process. None of the claims are drawn

to a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

At page 25 of the Brief, Appellants state that Krause et al does not disclose or suggest that IgY immunoglobulins bind to protein-wasting immunogens and that IgM and IgA immunoglobulins assist and help the binding process. Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. Krause et al discovered that monensin inhibited growth of *P. anaerobius* and *C. sticklandii* in the rumen of an animal but did not inhibit *C. aminophilium*.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. The rejection would have been under 35 USC § 102(b) had Krause et al teach egg antibodies such as IgY, IgM and IgA immunoglobulins that bind specifically to colony forming bacteria found in the rumen digestive track of food animal such as *P. anaerobius*, *C. sticklandii* and *C. aminophilium*. Krause *et al* teach colony-forming bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document, abstract, in particular).

Paragraph bridging pages 25 and 26 of the Brief, Appellants assert that there is no motivating directions or suggestion in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply. There are insufficient teachings of the above combined references and no evidence of a motivating force which would impel one skilled in the art to make and use the microbial adherence inhibitor produced by the claimed method. The numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to make a microbial

adherence inhibitor by the method of using IgY, IgM and IgA immunoglobulins in the entire contents of eggs to bind the IgY immunoglobulins to protein wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. The Examiner has completely failed to show any motivation to combine his references, either the Tokoro '895 reference with the Kaspers et al reference, the Pimental '489 reference and the Krause et al reference. There is certainly no "clear and particular" showing of motivation to combine.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive. The pending claims are drawn to a product by process. None of the instant claims are drawn to a method of promoting the growth of food animals by binding lgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

In contrast to appellants' assertion that there is no motivation to impel one skilled in the art to make and use the microbial adherence inhibitor, the teachings of the 895 patent pertaining to the IgY antibody that binds specifically to bacteria such as *E coli* and other pathogen and a method of making said antibody that binds to said bacteria for use as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal, the teachings of Krause indicating that colony forming bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion in the growth of livestock, and the teachings of the '489 patent pertaining to whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk would have led one of ordinary skill in the art at the time the invention was made to combine the references to make egg antibody that binds specifically to colony forming bacteria *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* instead of *E coli* and drying the entire content of the eggs without heaving to separate the eggs and albumin that are well known in the art. It is common knowledge that IgY types immunoglobulins are found in the yolk while IgM and IgA immunoglobulins are found in the albumin or egg white as taught by Kaspers *et al.* The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent

that some advantage or expected beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144.

Claims Rejection - 35 USC § 103

Claims 14-15, 17-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, abstract, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 1, 3, 5, 13, 16 and 19 and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

At pages 26-27 of the Brief, Appellants state that Claims 14, 15, 17, 18, 20 and 21 are claims dependent upon parent Claims 13, 16 and 19. The parent Claims 13, 16 and 19 include the method of drying the entire contents of the eggs. The dependent Claims 14-15, 17-18 and 20-21 more particularly define the drying process. The drying of the separated entire contents of the eggs is achieved by coating the dry feed carrier material with the entire contents of the eggs. Parent Claims 13, 16 and 19 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *C. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium*, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method of Claims 14-15, 17-18 and 20-21 includes the step of drying the separated entire contents of the harvested eggs with dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY, IgM and IgA immunoglobulins caused by a separate drying process to dry the entire contents of the harvested eggs before coating the dry carrier material with said contents of the eggs. The '878 disclose a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. Col. 9, lines 31-39. This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Appellants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is

distributed into the animal feed. The animal feed mixed with the coated carrier material is supplied to the animals. The carrier material is defined in Claims 15, 18 and 21 as a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp. Betz et al '867 disclose a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody. Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in claims 14, 17 and 20. The Examiner has failed to show any motivation to combine his references.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

The combined teachings of the '895 patent, Kasper et al, the '489 patent, and Krause et al have been discussed supra. The '895 patent (Tokoro et al) further teaches the separated yolk and albumen containing the antibody can be dried to form a powder by a conventional technique such as spray dried to form a powder or lyophilizing which does not cause a significant loss of activity of the antibody (see col. 6, lines 19-30, in particular). The '489 patent (Pimentel) further teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when they are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). The '489 patent teach antibody was mixed with 1 kg fine ground corn and then mixed with one metric ton feed (see col. 5, lines 1-2). The feed and water were supplied ad libitum (see col. 5, lines 3-4, in particular).

The claimed invention in claim 14 differs from the combined teachings of the references only in that the microbial adherence inhibitor wherein the drying of the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs.

The claimed invention in claim 15 differs from the combined teachings of the references only in that the microbial adherence inhibitor wherein the dry feed materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches high performance palatable horse feed carrier such as soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat the feed carrier material as taught by the '878 patent with the entire contents of said eggs containing antibody that binds to *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* as taught by the '895 patent, Kasper et al, the '489 patent, and Krause et al on the feed material such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular). Drying the entire content of the egg by coating carrier material such as feed is an obvious variation of the references teachings. In fact, the specification on page 23 discloses that whole egg can be dispended in water supplies, or in a dried format as whole powdered or use of a carrier to distribute the material (see page 23, Example 21). The

specification on page 26 at first paragraph discloses pasteurized whole egg is spray onto animal feed such as soybean hull to coat the soybean hull and then drying the crude soybean hulls.

In response to appellants' argument that Appellants coat a carrier material such as corn with the entire contents of the harvested eggs, the animal feed mixed with the coated carrier material is supplied to the animals, the '489 patent (Pimentel) teaches antibody was mixed with 1 kg fine ground corn (carrier) and then mixed with one metric ton feed (see col. 5, lines 1-2). The feed and water were then supplied ad libitum (see col. 5, lines 3-4, in particular). The '489 patent teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when they are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). The '878 patent also teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or *sprayed to coat directly onto carrier* such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

In response to appellant's argument that there is no motivation to combine the references, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, drying whole egg containing the desired antibodies in the form of dried egg powder or directly spraying the entire content of the egg containing the desired antibody onto animal carrier and then mixed with animal feed are taught by the '489 patent and the '878 patent. The choice of the particular feed as carrier is within the purview of one ordinary skill in the art given the teachings of the '867 patent that soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Claims Rejection - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) and Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892).

At pages 28-30 of the Brief, Appellant submits that Claim 5 defines a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. There is no disclosure in the '018 patent (Stolle et al) of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. Furthermore, the '018 does not disclose or suggest to one skilled in the art that the binding process is assisted or helped by IgM and IgA immunoglobulins. The Sugita-Konishi et al publication discloses IgY immunoglobulins from egg yolk from hens immunized with an infections pathogen is efficient in prevention of the disease caused by the pathogen. The IgY immunoglobulin was isolated from the egg yolk of hens immunized with 26 strains of bacteria. The investigation of the function of isolated IgY immunoglobulin was limited to three infectious bacterial strains. There is no disclosure in Sugita-Konishi et al of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins. The Yokoyama et al publication discloses isolation of antibodies from chicken egg yolk. Immunoglobulin G (IgG) egg yolk was diluted with distilled water and mixed with ethyl alcohol. The mixture was centrifuged. The supernatant which contained the IgG was purified. This process does not

suggest Appellants' microbial adherence inhibitor produced by the method defined in Claim 5. There is no disclosure in Yokoyama et al of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

In response to appellants' argument that there is no disclosure in the '018 patent (Stolle et al) or Sugita-Konishi et al or Yokoyama et al publication of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest

and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 5 differs from the teachings of the reference only in that the microbial adherence inhibitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and wherein the colony-forming immunogen is from the class consisting of *Listeria, Salmonella* and *Campylobacter.*

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent also teaches antibodies are mixed with feed carrier such as fine ground corn and then mixed with feed (see col. 5, lines 1-2, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference egg antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogens such as bacterium as *E coli, Listeria, Salmonella and Campylobacter*, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that avian antibody produced by

domesticated fowl which has been immunized against with any antigen of interested is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Yokoyama *et al* teach a microbial adherence inhibitor such as chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella. The reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen or bacteria such as the *E coli* as taught by the '895 patent for the bacteria such as *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent or the *Salamonella* as taught by Sugita-Konishi *et al* or the (OMP) of Salmonella as taught by Yokoyama *et al* for a microbial adherence inhibitor in the form of IgY, IgA and IgM antibody as taught by Kaspers *et al* to said *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent, Sugita-Konishi *et al* or Yokoyama *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Yokoyama *et al* teach IgY antibody to colony-forming immunogen such as Salmonella inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). Sugita-Konishi *et al* teach that egg antibody to *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). The '018 patent teaches that IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular) is useful for a method of passive immunity (See abstract, in

particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is the primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The antibodies from "overall ovum" as taught by the '895 patent (see summary of invention, col. 3, lines 50-53, in particular) obviously includes the IgY immunoglobulins in the yolk of the eggs and the IgM and IgA immunoglublins in the albumin of the eggs as evidence by the teachings of Kaspers *et al* (See abstract, in particular). Given the reference colony-forming immunogen is the same as the claimed immunogen, the reference method of making is the same as the claimed product by process, the end product antibodies from "overall ovum" obviously contain IgY, IgM and IgA are same as the claimed microbial adherence inhibitor. Thee inherent functions of the reference egg antibodies would also bind to the same immunogen and thereby preventing the bacteria from adhering to the digestive tract when administered to any living being.

Again, the claims are drawn to a product by process, not a method of using the product as argued. Further, a product is a product, irrespective of its intended use as argued.

In response to appellants' assertion that the secondary references do not teach the method of making the product, the method of making the product, in this case, the egg antibodies has been discussed in details in the '895 patent. Claim 5 differs from the teachings of the reference only in that the colony-forming immunogen is *Listeria, Salmonella*, and *Campylobacter* instead of *E coli*.

The '018 patent teaches various colony forming bacteria such as *E coli, Listeria, Salmonella* and *Campylobacter* and IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular) and bird antibodies are useful for a method of passive immunity (See abstract, in particular). Sugita-Konishi *et al* teach colony forming bacteria such as *Salamonella* is responsible for samonella enteritidis and a microbial adherence inhibitor such as egg antibody IgY inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach a microbial adherence inhibitor such as chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins

(OMP) of Salmonella. The reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

The teachings of the '895 patent indicating the simple, efficient and inexpensive method in making egg antibodies to any immunogen (See column 9, line 43-47; column 3, line 19-27), the '018 patent pertaining to the various colony forming bacteria such as *E coli, Listeria, Salmonella* and *Campylobacter* and egg antibody from the overall ovum that binds specifically to colony forming immunogen is useful for a method of passive immunity, the Sugita-Konishi reference pertaining to colony forming bacteria such as *Salamonella* is responsible for samonella enteritidis, the Yokoyama reference pertaining to Salmonellosis is caused by colony forming bacteria *Salmonella* would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144. The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07.

In response to appellants' argument that there is no disclosure of the binding process of IgY to the immunogen is assisted or helped by IgM and IgA immunoglobulins, neither the specification discloses any data, i.e. binding assay to show that binding of IgY to immunogen is increased or assisted or helped by IgM and IgA immunoglobulins. Further, the antibodies from "overall ovum" as taught by the '895 patent (see summary of invention, col. 3, lines 50-53, in particular) obviously includes the IgY immunoglobulins in the yolk of the eggs and the IgM and IgA immunoglublins in the albumin of the eggs as evidence by the teachings of Kaspers *et al* (See abstract, in particular).

Claims Rejection - 35 USC § 103

Claims 6-7, 12, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record,

Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

At page 30-31 of the Brief, Appellant submits that the separated entire contents of the harvested eggs are not dried before they are coated onto the dry feed carrier material. This avoids the reduction of the effectiveness of the IgY, IgM and IgA immunoglobulins caused by the process of drying the entire contents of the harvested eggs. It would not have been obvious to one skilled in the art to make a microbial adherence inhibitor by the method of providing a dry feed carrier material and coating the dry feed carrier material with the separated entire contents of the harvested eggs in view of the teachings of the combined references. Further, the Examiner has completely failed to show any motivation to combine the Tokoro '895 reference with the six secondary references. There is certainly no "clear and particular" showing of motivation to combine.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

In response to appellants' argument that the separated entire contents of the harvested eggs are not dried before they are coated onto the dry feed carrier material, the '489 patent (Pimentel) teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when they are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). The '489 patent teach antibody was mixed with 1 kg fine ground corn (carrier) and then mixed with one metric ton feed (see col. 5, lines 1-2). The feed and water were then supplied ad libitum (see col. 5, lines 3-4, in particular). The '878 patent also teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or *sprayed to coat directly onto carrier* such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The entire contents of the separated eggs are not dried before coating the dry carrier material with said contents of the eggs is merely an obvious variation of the reference teachings.

In response to appellants' argument that there is no motivation to combine the references, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07. The examiner's analysis has been discussed supra and is incorporated here by reference.

Claims Rejection - 35 USC § 103

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (or record, Jan 1992; PTO 1449) in view of Kaspers *et al* (of record, Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

At pages 31-32 of the Brief, Appellant submits that Claims 24 to 29 include a dry feed carrier material and coating the dry feed carrier material with the separated entire contents of the harvested eggs. The entire contents of the separated eggs are not dried before coating the dry carrier material with said contents of the eggs. Appellants' analysis, supra, concerning the primary reference, Tokoro '895, and secondary references, Kaspers et al, Pimental '489, Stolle et al '018, Krause et al, Adalsteinsson et al '878 and Betz et al '867, are applicable to the rejection of Claims 24 to 29. The inclusion of a dry feed carrier material and coating the material with the entire contents of harvested eggs is not shown or suggested by the prior art, either alone or in combination. Further, there is no "clear and particular" objective evidence of record showing motivation to combine the myriad references.

Appellants' arguments filed 10/30/05 have been fully considered but are not found to be persuasive.

In response to appellants' argument that the separated entire contents of the harvested eggs are not dried before they are coated onto the dry feed carrier material, the '489 patent (Pimentel) teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when they are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). The '489 patent further teaches antibody was mixed with 1 kg fine ground corn (carrier) and then mixed with one

metric ton feed (see col. 5, lines 1-2). The feed and water were then supplied ad libitum (see col. 5, lines 3-4, in particular). The '878 patent also teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or *sprayed to coat directly onto carrier* such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The entire contents of the separated eggs are not dried before coating the dry carrier material with said contents of the eggs is merely an obvious variation of the reference teachings.

In response to appellants' argument that there is no motivation to combine the references, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07. The examiner's analysis has been discussed supra and is incorporated here by reference.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Phuong N Huynh, PhD

Conferees:

Christina Chan
SPE, Art unit 1644

James Housel
SPE, Art unit 1648